

### REMARKS

Before entry of this Amendment and Response, the status of the application is as follows:

- The drawings are objected to under 37 CFR 1.83(a) for failing to show every feature of the invention specified in the claims.
- Claims 10 and 19 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,876,417 to Devonec, *et al.* (hereinafter “Devonec”).
- Claims 11 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Devonec in view of U.S. Patent No. 4,973,301 to Nissenkorn (hereinafter “Nissenkorn”).
- Claims 11 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Devonec in view of U.S. Patent No. 6,033,413 to Mikus, *et al.* (hereinafter “Mikus”).
- Claims 13-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Devonec in view of Mikus and further in view of U.S. Patent No. 6,238,430 to Klumb, *et al.* (hereinafter “Klumb”).

Previously withdrawn claims 1-9 and 18 have been canceled without prejudice to their subsequent reintroduction into this case or their introduction into a related application. Claims 10-12, and 19 have been amended. New claims 20-26 have been added.

Claims 10-12 and 19 have been amended to more clearly describe the nature of the claimed invention. Support for amended claims 11 and 12 and new claims 20 and 21 can be found at least in the first full paragraph on page 12, and in FIGS. 1, 2, and 10-12. Support for new claim 22 can be found at least in the first full paragraph on page 11, and in FIGS. 7-9. Support for new claims 23 and 24 can be found at least in the first full paragraph on page 10, and in FIG. 2. Support for new claim 25 can be found at least in the second paragraph on page 4, the second paragraph on page 10, and in FIG. 23. Support for new claim 26 can be found at least in

claim 12, as originally filed. Applicants submit that the amendments introduce no new matter. Upon entry of this paper, claims 10-15 and 19-26 will be pending and under consideration.

### **Objection to Drawings**

The drawings are objected to under 37 CFR 1.83(a) for failing to show every feature of the invention specified in the claims. Without acquiescing to the characterization of the drawings or claims and in order to expedite prosecution, Applicants have amended claims 10 and 19 to remove the term “single.” Upon entry of this amendment, Applicants believe that the objection to the drawings is moot and no corrected drawings are necessary. Accordingly, Applicants respectfully request reconsideration and withdrawal of this objection.

### **Rejections Under 35 USC § 102(e)**

Claims 10 and 19 are rejected under 35 U.S.C. § 102(e) as being anticipated by Devonec. Applicants respectfully traverse.

Independent claims 10 and 19 each recite, in part, a prostatic stent-catheter system including a stent that is sized for placement substantially within the prostatic section of the urethra with its distal terminating end located proximal of the external sphincter.

In contrast, Devonec appears to disclose a catheterization means 2 that comprises an upper element 8 and a lower element 9 connected by a deformable connection means 14. See Devonec, col. 4, lines 8-17, and FIG. 1. The upper element 8 is intended to be placed in the upper part of the urethral channel on one side of the striated muscular sphincter (i.e., the external sphincter), and the lower element 9 is intended to be placed in the lower urethral channel on the opposite side of the striated muscular sphincter. See Devonec, col. 4, lines 8-12, and FIGS. 7-9. The distal terminating end of the catheterization means 2 according to Devonec (i.e., lower element 9) is adapted to fit in the bulbar segment of the urethra on the distal side of the external

sphincter, and the connection means 14 is adapted to reside in the orifice of the sphincter. See Devonec, col. 4, lines 14-17, col. 7, lines 33-36, and FIGS. 7-9.

Nowhere does Devonec teach or suggest a stent that is sized for placement substantially within the prostatic section of the urethra with its distal terminating end located proximal of the external sphincter. In view of this structural difference between Applicants' claimed invention and the device disclosed in Devonec, the prostatic stent-catheter system of the present invention is not anticipated by Devonec.

In view of the foregoing, Applicants submit that claims 10 and 19 are not anticipated by Devonec. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

**Rejections Under 35 USC § 103(a)**

1. Claims 11 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Devonec in view of Nissenkorn. Applicants respectfully traverse with respect to the claims, as amended.

Amended claims 11 and 12 are each directed toward a prostatic stent-catheter system that includes a stent having a retaining member extending from the proximal portion of the stent. The retaining member includes a proximal end defining a structure for receiving a pushing device.

The proximal portion of the Devonec device (i.e., the upper tubular element 8) appears to have a smooth, continuous outer surface. See Devonec, FIGS. 1-12. Devonec does not disclose a retaining element on the upper tubular element 8. Further, Devonec does not suggest the need for a retaining element on the upper tubular element 8, because the upper tubular element 8 is held in place within the urethra by the striated muscle sphincter 13 closing around the connecting

element 14. See Devonec, col. 7, lines 33-36. Thus, Devonec does not teach or suggest a stent having a retaining member extending from the proximal portion of the stent.

The intraurethral catheter (IUC) 1 according to Nissenkorn includes a central tubular portion 2 with integral proximal 3 and distal 4 crowns and a hollow inner tube 7 running through its length. See Nissenkorn, col. 2, lines 48-53, and FIG. 1. The proximal crown 3 is intended to sit within the bladder 8 to prevent distal displacement of the IUC 1 (see Nissenkorn, col. 2, lines 58-61, and FIG. 4); however, the proximal crown 3 does not include a proximal end defining a structure for receiving a pushing device. The IUC 1 is introduced into a patient's urethra by pushing the IUC 1 through a Teflon sheath 30 using an obturator 34. See Nissenkorn, col. 4, lines 18-29. The obturator 34 appears to contact the distal end of the IUC 1 as it pushes the IUC 1 through the Teflon sheath 30 (see Nissenkorn, FIG. 6.); however, Nissenkorn is silent with respect to a structure for receiving a pushing device. Nowhere does Nissenkorn teach or suggest a stent that includes a proximal end defining a structure for receiving a pushing device.

As discussed above, there is no suggestion or motivation to add a retaining member to the Devonec catheter, because the catheter of Devonec is held in place within the urethra by another means (i.e., the connecting member 14). In fact, Devonec specifically discloses that the catheter is positioned in relation to the striated muscular sphincter, and not in relation to the neck of the bladder (see Devonec, col. 2, lines 54-61), as disclosed by Nissenkorn. Thus, there is no suggestion or motivation to combine the teachings of Devonec and Nissenkorn and, in fact, Devonec teaches away from adding a retaining member to the proximal end of the catheter that would reside within the bladder neck, as disclosed by Nissenkorn. See, Nissenkorn, FIG. 4.

Furthermore, even if such suggestion or motivation were to exist, which it does not, neither Devonec nor Nissenkorn, alone or in proper combination, teaches or suggests a stent

having a retaining member extending from the proximal portion of the stent, wherein the retaining member comprises a proximal end defining a structure for receiving a pushing device.

In view of the foregoing, Applicants submit that claims 11 and 12 are patentable over Devonec in view of Nissenkorn. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

2. Claims 11 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Devonec in view of Mikus. Applicants respectfully traverse with respect to the claims, as amended.

As discussed above, Devonec fails to teach or suggest a stent having a retaining member extending from the proximal portion of the stent, as recited in claims 11 and 12. In fact, Devonec teaches away from adding a retaining member to the proximal end of the disclosed device. Mikus fails to cure this deficiency.

Mikus appears to disclose a stent delivery system 8 that includes a catheter inner shaft 9, a catheter outer shaft 10, and an expandable mesh basket type anchor 14 secured to the distal tip of the inner shaft 9. See Mikus, col. 3, lines 15-28, and FIGS 2-7. The stent 7 is made of a nitinol alloy and is wound around the catheter outer shaft 10. See Mikus, col. 4, lines 31-33, col. 5, lines 5-8, and FIGS. 5, 7, and 9.

Mikus does not teach or suggest a stent having a retaining member extending from its proximal portion. The stent 7 according to Mikus is a memory-metal coil wrapped around the outside of the catheter outer shaft 10, and does not include a retaining member. It appears that the stent 7 is held in place by radial expansion against the prostatic urethra (see Mikus, col. 6, lines 48-52), thereby eliminating the need for a retaining member. The mesh basket type anchor 14 is connected to the stent delivery system 8, not the stent 7. In addition, the anchor 14 is

disposed within the bladder neck 5a (see, Mikus, FIGS. 6 and 7), contrary to the teachings of Devonec. Thus, neither Devonec nor Mikus, alone or in proper combination, teaches or suggests a stent having a retaining member extending from the proximal portion of the stent.

Additionally, as discussed above, Devonec fails to teach or suggest a retaining member comprising a proximal end defining a structure for receiving a pushing device. Since Mikus fails to teach or suggest a retaining member extending from the proximal portion of the stent, it follows that Mikus, alone or in proper combination with Devonec, also fails to teach or suggest a retaining member comprising a proximal end defining a structure for receiving a pushing device.

In view of the foregoing, Applicants submit that claims 11 and 12 are patentable over Devonec in view of Mikus. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

3. Claims 13-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Devonec in view of Mikus and further in view of Klumb. Applicants respectfully traverse with respect to the claims, as amended.

Claim 13, which depends directly from claim 12, recites, in part, a stent having a retaining member extending from the proximal portion of the stent. As discussed above, neither Devonec nor Mikus, alone or in proper combination, teaches or suggests a stent having a retaining member extending from the proximal portion of the stent. Klumb fails to cure this deficiency.

Klumb appears to disclose, in part, a catheter assembly 2 including a catheter 4 for delivering a stent 38 into a blood vessel of a patient. The stent 38 is a coil-type stent, typically made of nitinol wire, which is wrapped around the catheter shaft 18. See Klumb, col. 6, lines 23-36, and FIGS. 1 and 13-15. Klumb does not teach or suggest a stent having a retaining member

extending from the any portion of the stent. Thus, Devonec, Mikus, and Klumb, alone or in proper combination, fail to teach or suggest a stent having a retaining member extending from the proximal portion of the stent.

Additionally, as discussed above, neither Devonec nor Mikus, alone or in proper combination, teaches or suggests a retaining member comprising a proximal end defining a structure for receiving a pushing device. Since Klumb fails to teach or suggest a retaining member extending from the proximal portion of the stent, it follows that Klumb, alone or in proper combination with Devonec and/or Mikus, also fails to teach or suggest a retaining member comprising a proximal end defining a structure for receiving a pushing device.

In view of the foregoing, Applicants submit that claim 13, along with claims 14 and 15, which depend directly therefrom, are patentable over Devonec in view of Mikus and Klumb. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

#### **New Claims 20-26**

New claims 20-24 depend directly or indirectly from independent claim 10. Claim 25 is a new independent claim and claim 26 depends therefrom. As discussed above, independent claim 10 is patentable; therefore, new claims 20-24 are also patentable as a matter of law. Claims 25 and 26 are patentable at least for the reasons discussed above. Additionally, new claims 20-26 are patentable, because none of the cited references, alone or in proper combination, teaches or suggests all of the features recited in claims 20-26. In addition, Applicants note that the subject matter of new claims 20-26 is shown and described with respect to FIGS. 1 and 2, the previously elected Species A. Accordingly, Applicants respectfully request allowance of claims 20-26 in due course.

**CONCLUSION**

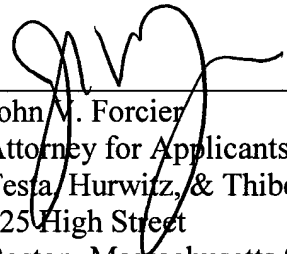
In view of the foregoing, Applicants respectfully request reconsideration, withdrawal of all grounds of objection and rejection, and allowance of claims 10-15 and 19-26 in due course.

The Examiner is invited to contact Applicants' undersigned representative by telephone at the number listed below to discuss any outstanding issues.

Respectfully submitted,

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